DIABETIC NUTRITIONALS AND METHOD OF USING

CROSS REFERENCE

This application is related to the Carbohydrate System and a Method for Providing Nutririon to a Diabetic, application Ser. No. 09/524,716, filed concurrently herewith by Wolf et al., the contents of which are hereby incorporated by reference.

The instant invention relates to solid matrix nutritionals designed for a person with diabetes. The matrix nutritional comprises a two component carbohydrate system which blunts the postprandial glycemic response. The solid matrix nutritional may be administered to a diabetic in the form of cereal, bread, cookies, muffins, bagels, biscuits, crackers and bars. Particularly, the present invention is directed to a nutritional bar designed for the person with diabetes which incorporates the two component carbohydrate system. The invention further relates to a method of delivering nutrition to an individual diabetes.

BACKGROUND

Primary treatment for glucose intolerance is strict adherence to a diet which minimizes postprandial glucose response, and in many cases, use of medications (insulin or oral hypoglycemic agents).

Before 1921, starvation was the only recognized treatment of diabetes mellitus (DM). Since the discovery of exogenous insulin, diet has been a major focus of therapy. Recommendations for the distribution of calories from carbohydrate and fat have shifted over the last 75 years. Based on the opinions of the time, the best mix to promote metabolic control are listed in Table 1 below.

TABLE 1

History of Recommended Caloric Distribution of Persons with DM

Year	Carbohydrate (%)	Protein (%)	Fat (%)
1921	20	10	70
1950	40	20	40
1971	45	20	35
1986	50–60	12–20	30
1994	*	10–20	*^

*based on nutritional assessment
^<10% saturated fat

Early recommendations limited dietary carbohydrate, because glycemic control was generally better with this type of regimen. However, over the years researchers found that low-carbohydrate, high-fat diets were associated with dyslipidemias and cardiovascular disease, because most high-fat diets consumed in industrialized countries were high in saturated fat. In 1950, the American Diabetes Association (ADA) recommended increasing the proportion of calories provided by carbohydrate to lower cardiovascular risk. While the risk for cardiovascular disease might be diminished by this strategy, research demonstrated that not all persons with DM respond favorably from the standpoint of metabolic control. In addition, the saturated fat being consumed continued to contribute to cardiovascular risk. The ADA's recommendation to restrict total fat, without regard to type of fat was challenged in the late 1980s by investigators and participants in the National Institutes of Health (NIH) Consensus Development Conference on diet and exercise in patients with type 2 DM. The recommendation of a carbohydrate-rich diet for all persons with DM also was

criticized because the theory that high-carbohydrate diets improve glycemic control and insulin sensitivity was not accepted due to inconclusive evidence. The NIH Conference led to the investigation of other dietary therapies, which resulted in a radical change in the 1994 ADA nutrition recommendations. The new ADA guidelines emphasize individualization of diet strategies. The purpose is to achieve optimal glycemic and metabolic control by varying the proportion of calories provided by the macro nutrients. The proportion selected depends on goals for glycemic control, dietary preferences and response to the diet.

The American Diabetes Association (ADA) currently recommends a diet in which protein is the same as that for the general population and accounts for 10% to 20% of total calories. With protein contributing 10% to 20% of the total calories, 80% to 90% of the total calories remains to be distributed between carbohydrate and fat. The carbohydrate/fat mix is individualized according to dietary preference, treatment goals, metabolic control and the presence of other medical conditions. However, the ADA does make a recommendation for the various types of fat in the diet. Specifically, saturated fat should contribute less than 10% of total calories, and polyunsaturated fat contributing no more than 10% of total calories. The remainder of fat calories should come from monounsaturated fat and the daily intake of cholesterol should be limited to less than 300 mg. The recommendation for fiber intake is the same as for the general public with approximately 20 to 35 g/day of dietary fiber from a variety of food sources. The micro nutrient requirements of otherwise healthy persons with DM will likely be met by consuming the amounts suggested by the RDIs. The relationship of the minerals chromium and magnesium to management of DM has been the focus of much research. Individuals considered at risk for micro nutrient deficiencies should be evaluated to determine if supplementation is necessary.

Products designed as nutritionals for the person with diabetes are commercially available. These nutritional products are typically liquids or in a solid form such as nutritional bars and baked goods. The solid forms have an advantage over liquid nutritionals as the solid form does not pass through the stomach as rapidly as a liquid. Therefore, the fat content of the solid forms may be decreased as the fat is not required to slow down the passage of nutrients from the stomach. Additionally, the commercial nutritional bars incorporate various complex multi-component carbohydrate systems which are digested at different rates thereby blunting the absorption curve of carbohydrates after a meal.

Ensure® Glucerna® Nutritional Bars (Ross Products Division of Abbott Laboratories, Columbus Ohio) is a complete, balanced nutritional designed specifically for people with diabetes. Soy protein, calcium caseinate and corn protein make up 14% of total calories as protein; high fructose corn syrup, honey, microencapsulated guar gum, crisp rice, maltodextrin, soy polysaccharide, sucrose, glycerin, polydextrose and oat bran make up 61% of total calories as carbohydrate; and partially hydrogenated soy and cottonseed oils, high oleic safflower oil, canola oil and soy lecithin make up 25% of total calories as fat. Microencapsulated guar gum, soy polysaccharide, cocoa powder and oat bran contribute 4 g total dietary fiber per 1.34 oz bar. One bar provides at least 15% of the RDIs for 24 key vitamins and minerals. The product also contains the ultra trace minerals selenium, chromium and molybdenum.

Choice dm® Bar (Mead Johnson & Company, Evansville, Ind.) is a nutritional bar with fiber, antioxidants and 24 essential vitamins and minerals for people with diabetes.